

## Sphincter Sparing Techniques for Treatment of Transsphincteric Anal Fistula

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### ABSTRACT

**Background:** anal fistula is a common proctologic problem. It is a common cause of chronic irritation to both patients and surgeons. It is a disease of antiquity. Even with all that work and research, started 2500 years ago, or may be more, man didn't find the ideal treatment for perianal fistulas.

**Objective:** The purpose of this study is to evaluate sphincter saving techniques used in management of transsphincteric anal fistula as regard rapid recovery, incidence of postoperative stool incontinence and recurrence rate.

**Patients and Methods:** our study was a prospective study of 60 patients who had transsphincteric anal fistula and were admitted to Al-Azhar University Hospitals from July 2017 till January 2019. The patients were divided into 3 groups according to the management procedure, group A was managed by seton technique, group B was managed by ligation of transsphincteric fistula tract (LIFT) and group C was managed by endorectal advancement flap (ERAFl).

**Results:** there were no differences of demographic data and characters of fistula among the three groups, however some differences were noticed regarding postoperative morbidity due to early complication including urine retention, bleeding, hematoma, infection and wound disruption but it was not statistically significant, there were statistically significant difference regarding postoperative pain, recurrence and incidence of stool incontinence.

**Conclusion:** high transsphincteric fistula warrants more sphincter sparing techniques to avoid the most likely sphincter dysfunction which could be happened after traditional surgery like fistulectomy and cutting seton for this type of complex anal fistula.

**Keywords:** Anal fistula; sphincter sparing; seton, LIFT, Advancement flap.

### INTRODUCTION

Anal fistula, fistula in ano or sometimes called fistula around the anus is a hollow channel lined with granular tissue that connects the primary aperture within the anal canal to a secondary opening in the skin around the anus. Secondary spaces may be multiple and can extend from the same basic opening<sup>(1)</sup>.

Perianal fistula is a common condition. It has an incidence of 5.6 per 100000 in women and 12.3 per 100000 in men, the disease occurs predominantly in the third and fourth decade of life. It is believed that infection of the intersphincteric glands is the initiating events in fistula in ano in a process known as the cryptoglandular hypothesis<sup>(2)</sup>.

Numerous methods can be employed for diagnosis of perianal fistula, the basic principles and procedures of which include the application of Goodsall's rule, careful physical examination (to find any cord like structure or external orifices, etc.), probing of the tract, endosonography and a variety of injection and radiologic techniques<sup>(3)</sup>.

The management of perianal fistula has been documented in the literature for thousands of years, dating back to the time of Hippocrates in 400 BC<sup>(4)</sup>. However anal fistula repair still remains challenging. Persistent fistulae occur in up to 30% of cases following definitive surgery despite many improvements in surgical skills and techniques<sup>(5)</sup>.

The ideal way to treat the anal fistula is to cure the disease without any risk of fecal incontinence. The different surgical techniques used in treating anal fistula can be divided into 2 groups: sphincter-sacrificing and sphincter-sparing techniques. The sphincter-sacrificing techniques, with or without immediate repair, have a high healing rate but also a high postoperative incontinence rate, while the sphincter-sparing techniques have varied healing rates but little or no resultant incontinence. The impairment of continence has an effect on quality of life, so the sphincter-sparing techniques are now popular<sup>(6)</sup>.

The management of anorectal abscess and anal fistula has changed markedly with time. Invasive methods with high resulting rates of incontinence have given way to sphincter-preserving methods that have a much lower associated morbidity<sup>(7)</sup>.

However, the results of sphincter sparing methods have been variable, and no one procedure is superior to the others absolutely. It is worth our concern that the goal of any treatment procedure is to obliterate the tract and to have low recurrence rates while maintaining full continence<sup>(8)</sup>.

### AIM OF THE WORK

The aim of the study was to evaluate the sphincter sparing techniques for management of transsphincteric anal fistula and to compare between the most common

applies procedures: seton technique, ligation of transsphincteric fistula tract (LIFT) and endorectal advancement flap (ERAF).

## PATIENTS AND METHODS

This was a prospective study comparing seton technique, LIFT and ERAF in patients with transsphincteric anal fistulas of cryptoglandular origin. Patients were recruited from Al-Azhar University Hospitals from July 2017 till January 2019. The study population consisted of adult patients with transsphincteric anal fistulas. Inclusion criteria were age above 18 years and cryptoglandular origin. Patients were excluded from the study if they had specific fistulas due to any disease such as Crohn disease, malignancy, or tuberculosis. **The study was performed after approval of the Al-Azhar University Ethical Committee. Informed consent was obtained from each patient before randomization.** Sixty patients were randomly assigned to 3 equal groups, group A was managed by seton technique, group B was managed by ligation of transsphincteric fistula tract (LIFT) and group C was managed by endorectal advancement flap (ERAF). No patients were lost during follow-up in all groups, and all 60 patients were included in the analysis.

Preoperative evaluation was done by history taking of any degree of fecal incontinence and assessment of the continence by Wexner score<sup>(9)</sup>, clinical examination including local inspection, digital rectal examination and proctoscopy. The degree of sphincter involvement was determined by using MRI to outline the fistula tract and measure sphincter involvement.

### **Surgical Procedures**

Surgeries were performed by experienced surgical teams under supervision of consultant surgeons. All procedures were performed with the use of general or locoregional anesthesia. The internal fistula tract opening was first identified during surgery. For seton technique (group A), after identification of the external and internal openings of the fistulous track, excision of external part of the fistula was done till reaching the external anal sphincter, remain part of the tract encircled by size 1 prolene and tightened. The seton was securely tied, usually with moderate tension, subsequent tightening of the ligature was achieved by application of hangman's knot in the majority of patients. Another alternative technique was done by insertion of multiple setons initially, securing only one. As each cuts through, another one was tied. The cutting seton required further follow-up visits for subsequent tightening of the seton to achieve the desired effect.

For LIFT (group B), a metallic probe was inserted into the external opening and passed gently through the track to exit through the internal opening. The intersphincteric groove was then identified, and a small circumanal incision (2 cm) overlying the fistula tract was made to enter the space between the internal and external sphincters. Diathermy and blunt dissection were used to dissect the intersphincteric plane and reach the probed fistula tract. The dissection was kept as close as possible to the internal anal sphincter (IAS), and 2 small retractors were used to open the space, gently separating the sphincters. The fistula tract was then encircled by using a right-angle clamp, and 2 absorbable sutures (2/0 Vicryl) were used to doubly secure and close the fistula tract as close as possible to the lateral margin of IAS and the medial margin of the external anal sphincter, followed by dividing the tract between these 2 sutures. To confirm the closure of both the internal and external fistula tract, hydrogen peroxide was injected from the internal and the external orifices. The intersphincteric plane was closed in 2 layers (muscle approximation and skin) by using interrupted 3/0 Vicryl. The external and internal orifices were left open to allow drainage. The external opening induration was excised and left opened wide.

The endorectal advancement flap (ERAF) (group C) was done according to the following technique, the internal opening was excised followed by mobilization of a 2- to 3-cm broad-base rectal flap including the mucosa, submucosa, and partial thickness of the IAS muscle. The flap was mobilized sufficiently to cover the internal opening with overlap. Hemostasis was performed to prevent a hematoma under the flap. The internal opening was closed with a layer of interrupted sutures placed in the internal sphincter muscle (using 2/0 polyglactin). The integrity of this layer of the repair was checked by squirting saline through the external opening, then the mucosa muscular flaps were closed, obliterating dead space with the sutures. The external opening induration was excised and left opened wide.

### **Postoperative Care**

Patients in the seton (group A) and LIFT (group B) were allowed to have a normal diet on the day of surgery and were discharged on the same day or on the next morning. Patients in the ERAF (group C) started oral liquids 1<sup>st</sup> postoperative day and soft diet 2<sup>nd</sup> postoperative day and fed a normal diet 3<sup>rd</sup> day before discharge. Intravenous antibiotics were continued until discharge. Oral antibiotics were prescribed for 5 days for all patients after discharge plus laxatives and analgesia.

Patients were planned for followed up at 2 weeks, 4 weeks, 12 weeks, 6 months, and 1 year. During

follow-up, the closure rate was determined by clinical examination. The fistula was rated as completely healed if the external and the internal openings were closed and no discharge was experienced, it was considered persistent if not closed at any point of follow-up, whereas it was considered recurrent if it was completely healed at any point followed by redischarge.

The primary end points of the study were fistula closure, recurrence and continence. Continence was evaluated preoperatively and postoperatively by using the Wexner score.

Secondary end points were morbidity due to postoperative pain and early postoperative complication as bleeding, wound disruption, hematoma, urinary retention and infection. Pain was graded by patients by using the visual analog scale (0, no pain; 10, worst imaginable pain)

#### **Statistical Analysis**

The collected data was revised, coded, tabulated and introduced to a PC using Statistical Package for Social Science (SPSS 15.0.1 for windows; SPSS Inc, Chicago, IL, 2001). Data were presented and suitable analysis was done according to the type of data obtained for each parameter.

**Table (1): Patient characteristics**

<b>Characteristic</b>	<b>Group A</b>	<b>Group B</b>	<b>Group C</b>	<b>P value</b>
<b>Age y (mean)</b>	41.15	42.85	39.90	0.617
<b>SD</b>	± 10.266	± 9.270	± 8.855	
<b>Sex male</b>	15 (75%)	13(65%)	16 (80%)	0.564
<b>female</b>	5 (25%)	7 (35%)	4 (20%)	
<b>Smoking</b>	12 (60%)	11(55%)	13 (65%)	0.820
<b>Diabetes</b>	2 (10%)	4 (20%)	3 (15%)	0.687
<b>Low TS</b>	6 (30%)	7 (35%)	5(25%)	0.797
<b>High TS</b>	14 (70%)	13 (65%)	15 (75%)	
<b>Recurrent</b>	2 (10%)	4 (20%)	1 (5%)	0.337

TS (transsphincteric anal fistula).

Table (2) is summarizing the rate of early postoperative complications of each group, although there was some obvious differences between the groups but statistically still insignificant.

**Table (2): Early postoperative complications in each group**

<b>Complication</b>	<b>Group A N. Percent.</b>	<b>Group B N. Percent.</b>	<b>Group C N. Percent.</b>	<b>P value</b>
<b>urine retention</b>	2 (10%)	0 (0%)	3 (15%)	0.226
<b>bleeding</b>	1 (5%)	1 (5%)	2 (10%)	0.774
<b>Wound Hematoma</b>	0 (0%)	1 (5%)	2 (10%)	0.361
<b>Wound infection</b>	0 (0%)	3 (15%)	2 (10%)	0.226
<b>Wound disruption</b>	0 (0%)	0 (0%)	3 (15%)	0.042

Complete healing was achieved in 19 patients (95%) in group A, 19 patients (95%) in group B and 17 patients (85%) in group C. ( $p = 0.431$ ). 1 patient in group A, 1 patient in group B and 3 patients in group C had persistent fistulas. Mean healing time was 8.74 weeks in group A, 4.53 weeks in group B and 5.12 weeks in group C, ( $p = 0.023$ ).

**Paired t-test** was used to assess the statistical significance of the difference between two means measured twice for the same study group.

**Wilcoxon signed rank test** was used to assess the statistical significance of the difference of an ordinal variable (score) measured twice for the same study group.

- **P- value:** level of significance
- $P > 0.05$ : Non significant (NS).
- $P < 0.05$ : Significant (S).
- $P < 0.01$ : Highly significant (HS).

#### **RESULTS**

There were no significant differences between the groups with regard to demographic data and characters of anal fistula (**Table 1**).

There was no statistical significant difference regarding the mean follow-up periods for patients in each group, in group A was 12.65 months, group B was 12.85 months and group C was 12.70 months.

Postoperative pain was assessed by use of the visual analog scale after 1 week. There was significantly higher mean pain score in group C (5.05) than group A (3.95) and group B (3.30).

As regards the fistula recurrence after surgery there were 8 cases of recurrence in all patients distributed as follows: One case (5%) in group A, was noticed due to slipping of the seton suture and failure of wound healing. Two cases (10%) in group B, one due to persistent discharges after abscess drainage and the other one noticed at 5<sup>th</sup> month of follow up after complete healing. Five cases (25%) in group C, three of them due to failure of healing with persistent discharges and two cases reported after complete healing at 4<sup>th</sup> and 7<sup>th</sup> month of follow up. Table (3) shows comparison between the groups regarding fistula recurrence, there was significant higher recurrence rate in group C.

**Table (3): Comparison between each group as regard recurrence**

	Group (A)		Group (B)		Group (C)		<b>P- value</b>
	n.	Percentage	n.	Percentage	n.	Percentage	
<b>Recurrence</b>	1	5%	2	10%	5	25%	0.046

Functional outcome as disturbance of the baseline continence was reported in 5 patients, 4 patients (20%) in group A and 1 patient (5%) in group C, no incontinence was reported in group B (Table 4). In group A, 4 patients complained of worsening of their continence, 2 patients were complaining from staining on their underclothing, 1 patient with difficulty in holding gas, and 1 patient with inability to control liquid stool. While in group "C" there were only one patient with change in their continence with difficulty in holding gas. During follow up the continence status of the patients was improved except one case in group A with liquid stool incontinence still under follow up.

**Table (4): Comparison between each group as worsening of continence**

	Group (A)		Group (B)		Group (C)		<b>P- value</b>
	n.	Percentage	n	Percentage	n.	Percentage	
<b>Worsening of continence</b>	4	20%	0	0%	1	5 %	0.039

There was a highly significant increase in postoperative Wexner score in groups (A) by worsening of continence, while in group (B) and group (C) there was no statistical significant difference between the pre- and postoperative Wexner score as shown in table (5).

**Table (5): comparison between the pre and postoperative Wexner score in each group.**

<b>Patient groups</b>		<b>preoperative Wexner score</b>	<b>postoperative Wexner score</b>	<b>P value</b>
<b>Group A</b>	N	20	20	
	<b>Mean</b>	1.10	2.90	.005
	<b>Std. Deviation</b>	1.210	4.077	
<b>Group B</b>	N	20	20	
	<b>Mean</b>	1.05	1.10	
	<b>Std. Deviation</b>	0.759	0.718	.156
<b>Group C</b>	N	20	20	
	<b>Mean</b>	1.05	1.35	
	<b>Std. Deviation</b>	0.826	1.565	.121

## DISCUSSION

The goal of surgical management for perianal fistula is to effectively eradicate current and recurrent septic foci, associated epithelialized tracts and preserve continence. No single technique achieves these aims for all types of anal fistulas. It is often necessary to balance the degree of sphincter division and continence disturbance. An ideal procedure for treating a fistula-in-ano should be minimally invasive with minimal failure rates and morbidity<sup>(10)</sup>.

In our study there was evaluation of the most common sphincter preserving techniques (LIFT and ERAF) and also the classic procedure which is seton placement for management of transsphincteric anal fistula with trial of comparison among the 3 procedures.

**Madbouly *et al.***<sup>(11)</sup> reported significant postoperative pain score in advancement flap group (mean  $4.8 \pm 2.8$ ) compared with LIFT group (mean  $3.1 \pm 1.3$ ) in their study of management of transsphincteric anal fistula. In our study, postoperative pain was assessed by use of the visual analog scale. There was also significant difference in mean postoperative pain score, which was higher in group C (ERAF) ( $5.05 \pm 1.27$ ) than in group B (LIFT) ( $3.30 \pm .895$ ) and in group A (seton) ( $3.95 \pm 1.05$ ).

In the our study, early postoperative complications had developed for variant degree among the 3 groups, although it was statistically insignificant but incidence of some complications were noticed higher in special groups. Urine retention is a common postoperative complication for anorectal surgeries, it was reported in 2 patients (10%) of group A (seton) and 3 patients (15%) of group C (ERAF). It was mainly due to severe postoperative pain as a results of manipulations the sensitive anoderma. In addition some patient had prostatic hyperplasia. Incidence of wound infection was high in group B (LIFT) (3 patients 15%), in 2 patients of them mild infection noticed during surgery. Wound disruption was a common complication after advancement procedure, in group C, 3 patients (15%) reported wound disruption, this may be due to underlying infection, impaired blood flow or may be attributed to suture tension leading to flap devascularization.

**Amin *et al.***<sup>(12)</sup> study showed wound disruption in 3 patients (16%) out of 18 patients, the authors considered that incidence is low and this low percentage of cases who developed wound breakdown in their study was because they avoided the dead space and confirmed that the skin must be sutured using absorbable sutures, leaving open most of the site of external opening for drainage. Also **Perez *et al.***<sup>(13)</sup>

reported that their study cases did not suffer from wound disruption. That was due to reinforcement of the flap by continues sutures that had the role for protecting the flap from disruption.

Regarding overall cure (success) rate in our study, healing rate initially was 95 % of group A and group B but 85 % in group C it was high in group C mainly due to wound disruption. After follow up with reporting or recurrence, overall cure rate was 95% of group A, 90% of group B and 75% of group C.

Most of previous studies done on the different procedures for treatment of transsphincteric anal fistula were emphasizing on failure of the procedure (recurrence) and functional sphincter disorders (incontinence) as managing a complex fistula in ano can be a daunting task for most surgeons largely due to the two major dreaded complications: recurrence and fecal incontinence<sup>(14)</sup>.

In the current study recurrence developed in 8 patients, 1 patient (5%) of group A, 2 patients (10%) of group B and 5 patients of group C, it was significantly high in group C. Recurrence was mainly due to infection in group B and wound disruption in group C and in group A only 1 patient due to slipping of the seton suture.

Compared with the recurrence rate of 5% in group A (seton) at the end of our study, **Mentes *et al.***<sup>(15)</sup> had a recurrence rate of 35% at 1 month post-surgery and 0% by 3 months. In another study, complete healing occurred in all patients within 3 months; recurrent fistula was noted in one patient (3.3%) at 5 months while none developed incontinence. They concluded that treatment of high fistula-in-ano with a cutting seton is associated with a low complication rate and can be recommended as the standard treatment for high fistula in-ano<sup>(13)</sup>.

Some studies on LIFT procedures were done and reported variable results regarding recurrence. **Rojanasakul**<sup>(16)</sup> and **Ellis**<sup>(17)</sup>, each reported that the recurrence rate for the patients treated by the LIFT technique in their studies was 6%. **Tan *et al.***<sup>(18)</sup> reported recurrence rate of 14%. All the results of these studies are very near to our results.

In accordance with the current results, a study done by **Nelson *et al.***<sup>(19)</sup>, they reported recurrence in 17 (26%) patients out of 64. They did not explain the main cause of recurrence but mentioned some risk factors associated with recurrence like male gender 25%, previous treatment of fistula by seton 36%, Crohn disease 11% and HIV patient 5.8%). Also similar results were reported by **Perez *et al.***<sup>(13)</sup> on 30 cases who had been operated upon by advancement flap technique. Recurrence occurred in 10 (30%)

patients and was related to horse shoe fistula, missed tracts and failure to identify the internal opening prior to surgery.

Worsening of continence is considered the most serious complication following anal fistula management. In the current study, incontinence was reported significantly high in group A (seton) where 4 (20%) patients experienced different degrees of incontinence while only one (5%) patient in group C (ERAF), and no cases reported in group B (LIFT). Also there was significant difference between preoperative and postoperative Wexner score only in group A.

**Ritchie et al.** <sup>(20)</sup> revised 21 studies on cutting seton for transsphincteric anal fistula and found that the mean incontinence rates varied from 0% to 53%. Only one study reported no incontinence, if this report is removed, the incontinence rates ranged from 3% to 53%. Incontinence rates after treatment of transsphincteric fistula were 20.5% which looks similar to our results. In contrast to our study, another study done by **Kamrava and Collins** <sup>(21)</sup> showed that one patient (2%) subsequently developed fecal incontinence, and four (9%) developed a recurrent or persistent fistula in the same location. They concluded that adjustable cutting setons had a high success rate and low risk of complications.

**Limura and Giordano** <sup>(22)</sup> had revised 14 studies done on LIFT procedures since **Rojanasakul** <sup>(16)</sup> till **Dubsky et al.** <sup>(23)</sup> and found that no incontinence complications reported. This indicates the safety of the procedure on the sphincters.

Finally, in our study, we reported incontinence only in one (5%) of group C (ERAF), and this patient had mild degree of incontinence to flatus and fortunately improved with observation. Although advancement flap considered sphincter preserving technique but this mild degree of incontinence which was reported could be due to sphincter stretch during anal dilatation by retractors and significant internal sphincter muscle fibers division during mobilization of the flap. Similar results reported by **Perez et al.** <sup>(13)</sup> in 30 patients treated by advancement flap 2; (6.66%) patients reported minor alteration of anal continence due to instrumental anal dilatation and the study confirmed that there were associated risk factors for incontinence, like the complexity of the fistula, the type of surgery, a high and posterior internal opening, horizontal extension and female sex. This finding was attributed to the usage of anal retractors causing stretch injury and the part of the internal sphincter that is incorporated in the flap to give more strength. In a

study done by **Dubsky et al.** <sup>(23)</sup> they documented the causes of incontinence after endorectal advancement flap operation, which were partial division of internal sphincter during flap mobilization and sphincter trauma from anal dilatation during retraction for operative exposure.

## CONCLUSIONS

High transsphincteric fistula warrants more sphincter sparing techniques to avoid the most likely sphincter dysfunction which could be happened after traditional surgery for this type of complex anal fistula. LIFT procedure is a simplified sphincter sparing technique with promising early results in this study, but it should be delayed when there is local infection, even mild, and may be preceded by application of loose seton for eradication of sepsis and maturation of the tract. Endorectal advancement flap seems to be valid for treatment of transsphincteric anal fistula as it is considered safe and optional procedure preserving anal continence, yet the high recurrence rate associated with the advancement flap would be considered as a major drawback that limits its routine use in treatment of transsphincteric anal fistula.

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